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September 24, 2024

The Honorable Georgette Castner, U.S.D.J.
United States District Court
District of New Jersey – Trenton
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

RE: Hannah Lovaglio, et al. v. Kaitlan Baston et al.
Civil Action No.: 3:23-cv-21803

Dear Judge Castner:

In response to Your Honor's September 17, 2024 Order, please accept this correspondence as the Association for Creatine Deficiencies interest in appearing as amicus in the above matter.

The Association for Creatine Deficiencies ("ACD") is a 501(c)(3) nonprofit organization dedicated to raising awareness, supporting research, and advocating for individuals affected by Cerebral Creatine Deficiency Syndromes ("CCDS"). The ACD actively engages in state and federal lobbying efforts to promote policies that benefit the CCDS community. These efforts include advocating for newborn screening, funding for medical research, and improved access to treatments. They also collaborate with organizations such as the National Institutes of Health (NIH) and biotechnology companies to advance clinical studies and potential treatments.

Newborn screening ("NBS") is a public health program that was formally initiated in the United States more than 60 years ago. The purpose of newborn screening is to detect potentially fatal or disabling conditions in newborns as early as possible, often before the infant displays any signs or symptoms of a disease or condition. Such early detection allows treatment to begin immediately, which reduces or even eliminates the effects of the condition. Many of the conditions detectable in newborn screening, if left untreated, have serious symptoms and effects, such as lifelong nervous system damage; intellectual, developmental, and physical disabilities; and even death. The newborn screening is a non-invasive test where a few drops of blood are taken from the baby's heel within two days of birth. The blood drops are then placed on a NBS blood spot card that is then sent to the state's lab and tested for conditions on that state's newborn screening panel. The conditions that are tested for on the newborn screening panels require both immediate detection and immediate medical intervention to prevent irreversible medical consequences, including death.

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Every baby born in New Jersey must have a bloodspot screen taken within 48 hours of birth to test for 61 illnesses and congenital disorders. The NBS blood spot cards play a critical role in public health and in rare disease research that extends beyond the initial diagnosis. The bloodspot cards are used for quality assurance, such as the testing and validation of equipment, research for potentially lifesaving treatments, improving existing newborn screening tests and developing new newborn screening tests. The effectiveness of current screening would be severely weakened without the retention of dried bloodspot cards.

The ACD actively engages in state and federal lobbying efforts to promote policies that benefit the CCDS community. These efforts include advocating for newborn screening, funding for medical research, and improved access to treatments. They also collaborate with organizations such as the National Institutes of Health (NIH) and biotechnology companies to advance clinical studies and potential treatments.

The Plaintiffs in this case seek to mandate that New Jersey destroy all newborn screening bloodspot cards with no regard for the fact that the retention of same provides clear and tangible benefits to the public health without hindering the rights of parents and children. The ACD, an organization with extensive experience in NBS both nationwide and internationally, is uniquely able to address the issues in this lawsuit. Moreover, the ACD is uniquely equipped to provide firsthand accounts from individuals that have been profoundly impacted by newborn screening and the lack thereof. The perspective that the ACD can provide is unique and provides necessary insight into the necessity of balancing parental rights with the undeniable need to retain blood spot cards for quality control/validation and research for new treatments and cures.

For these reasons, the Association for Creatine Deficiencies respectfully submits that its interest warrants an amicus curiae appearance in this matter.

Respectfully submitted,

Erin Burke Cirelli

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CC: Client